UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

MARLON BOWLES	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No. 1:20-cv-07413
	)	
ABBVIE INC., ABBVIE 1-100 AND ABBOTT 1-100	)	
	)	
	)	
Defendants.	)	

DEFENDANT ABBVIE INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(6)

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Rules

Other Authorities

I. INTRODUCTION

This products liability case arises from Plaintiff's use of AbbVie's FDA-approved drug HUMIRA®. Because Plaintiff is a resident of and domiciled in Texas, the relevant events—the prescription of HUMIRA and his alleged injuries—took place in Texas. The applicable substantive law in this case is Texas law, which imposes a presumption that manufacturers of FDA-approved pharmaceutical drugs are not liable for the types of claims Plaintiff brings here. Tex. Civ. Prac. & Rem. Code Ann. § 82.007. While that presumption may be rebutted under certain limited exceptions, Plaintiff has failed to plead facts sufficient to establish any of those exceptions. Moreover, even if Section 82.007 does not bar all of Plaintiff's claims, some of his claims still fail for independent reasons.

AbbVie respectfully requests that the Court dismiss, with prejudice,[1] Plaintiff's Amended Complaint in its entirety.

II. BACKGROUND

HUMIRA is an FDA-approved drug that has been on the market for nearly two decades. As the Amended Complaint acknowledges, the FDA first approved HUMIRA for use (for

[1] This is AbbVie's second motion to dismiss in as many months. In response to AbbVie's first motion, [Dkt. Nos. 8, 9], Plaintiff filed his First Amended Complaint [Dkt. No. 17]. AbbVie now moves to dismiss Plaintiff's First Amended Complaint because it suffers from the same deficiencies as before. As shown below, allowing Plaintiff another chance to amend would be futile.

rheumatoid arthritis only) on December 31, 2002. *See* Pl. Am. Compl. [Dkt. No. 17], at ¶ 20.[2] In October 2005, the FDA approved the use of HUMIRA as a treatment for psoriatic arthritis.[3]

Between March and April 2018, Plaintiff "received a total of three doses of HUMIRA" to treat his psoriatic arthritis. Am. Compl. at ¶¶ 70-71. On April 27, 2018, Plaintiff was admitted to the hospital where he was diagnosed with (and treated for) "acute renal failure secondary [to] minimal change disease, nephrotic syndrome secondary to minimal change disease, acute glomerulonephritis, . . . and interstitial lung disease." *Id*. at ¶ 72-73. Plaintiff asserts that HUMIRA caused or contributed to the conditions for which he was hospitalized in April 2018 and subsequent health problems. The Amended Complaint purports to identify eight causes of action against AbbVie: (1) Strict Liability – Failure to Warn (¶¶ 78-80); (2) Negligence (¶¶ 81-119); (3) Breach of Implied Warranty (¶¶ 120-124); (4) Breach of Express Warranty (¶¶ 125-128); (5) Fraud (¶¶ 129-133); (6) Negligent Failure to Test (¶¶ 134-141); (7) Negligent Misrepresentation (¶¶ 142-148); and (8) Gross Negligence (¶¶ 149-162). AbbVie now moves to dismiss all eight of Plaintiff's claims under Federal Rule of Civil Procedure 12(b)(6).

III. RULE 12(b)(6) STANDARD

Federal Rule of Civil Procedure 12(b)(6) authorizes a court to dismiss a cause of action that fails "to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). To avoid dismissal under Rule 12(b)(6), the complaint must contain "sufficient factual matter, accepted as

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[2] *See also* U.S. Food and Drug Administration Website, Approval Letter for HUMIRA (Dec. 31, 2002) https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/adalabb123102L.htm (last visited Jan. 26, 2021). AbbVie's use of this FDA approval letter is appropriate at this stage because it is a matter of public record, is publicly available, and is subject to judicial notice. *See Vincent v. Medtronic, Inc.*, 221 F. Supp. 3d 1005, 1009 (N.D. Ill. 2016) (Considering, at the 12(b)(6) stage, an FDA approval letter and stating that "as publicly-available government agency determinations that appear on an agency website, these approvals by the FDA are subject to judicial notice.").

[3] U.S. Food and Drug Administration, Supp. Approval Letter for HUMIRA (Oct. 3, 2005) *available at* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2005/125057s0046ltr.pdf, attached as **Exhibit A**.

true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal citation omitted). "A claim has facial plausibility when the plaintiff pleads *factual content* that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (emphasis added). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* A conclusory assertion is a conclusion without "factual enhancement" to support the conclusion. *Id.* In other words, the complaint must offer more than an "unadorned, the-defendant-unlawfully-harmed-me accusation" to defeat dismissal. *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citations omitted)).

Although the court must accept well-pleaded facts as true, conclusory allegations are not entitled to a presumption of truth. *Id.* at 678-79. Additionally, when a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility." *Id.* (citation and quotations omitted). Finally, although Rule 8(a) requires only a "short and plain statement", that statement "must 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Fields v. Cty. of Cook*, No. 19-CV-02680, 2020 WL 5296926, at *3 (N.D. Ill. Sept. 4, 2020) (quoting *Twombly*, 550 U.S. at 555); *Brooks v. Ross*, 578 F.3d 574, 581-82 (7th Cir. 2009) (allegations must be specific enough to provide notice of the contours of a viable claim).

IV. ANALYSIS

A. Texas Substantive Law Applies in this Products Liability Case.

Texas has the most significant relationship to the case and, thus, its law applies. Because there is a conflict between Texas and Illinois law that is outcome determinative in this case, *see*

infra,[4] a choice-of-law analysis is necessary at this stage. *Riviana Foods, Inc. v. Jacobson Warehouse Co., Inc.*, No. 18-CV-06550, 2020 WL 2802877, at *6 (N.D. Ill. May 29, 2020) ("'a choice-of-law determination is required only when the moving party has established an actual conflict between state laws.'") (quoting *Spitz v. Proven Winners N. Am., LLC*, 759 F.3d 724, 729 (7th Cir. 2014)).

In products liability cases like this one, "Illinois follows the 'most significant relationship test' of the Restatement (Second) of Conflict of Laws ('Second Restatement') to resolve a choice-of-law issue." *Paulsen v. Abbott Labs.*, No. 15-CV-4144, 2018 WL 1508532, at *12 (N.D. Ill. Mar. 27, 2018) (citing *Suzik v. Sea-Land Corp.*, 89 F.3d 345, 348 (7th Cir. 1996)). The Second Restatement's choice-of-law analysis consists of a two-step process, in which the Court:

> (1) chooses a presumptively applicable law under the appropriate jurisdiction-selecting rule, and
>
> (2) tests this choice against the principles of § 6 in light of relevant contacts identified by general provisions like § 145 (torts).

Id. As explained below, an evaluation of each of these prongs establishes that Texas law governs.

1. *Texas Law is presumptively applicable because Plaintiff was injured in Texas.*

"[I]n Illinois there is a ***strong presumption*** that the law of the place of injury applies in a personal injury case, and this presumption is only overcome by 'showing a more or greater significant relationship to another state.'" *Id*. (quoting *Smith v. I-Flow Corp.*, 753 F. Supp. 2d 744, 747 (N.D. Ill. 2010) (emphasis added)). In this case, Texas is the place of injury.

[4] Specifically, the Texas Legislature enacted Section 82.007 of the Texas Civil Practice and Remedies Code, which provides manufacturers of FDA-approved drugs with a presumption of non-liability in warnings-based products liability claims. Illinois does not have a similar statutory presumption.

As the Amended Complaint makes clear, Plaintiff is a domiciliary and citizen of Texas. Am. Compl. at ¶ 7. Tellingly, while Plaintiff amended his Complaint to expressly plead that Illinois law applies, *id*. at ¶ 14, he ***does not allege*** that he was prescribed HUMIRA outside of Texas, that he filled his HUMIRA prescription outside of Texas, received and reviewed information regarding HUMIRA outside of Texas, injected HUMIRA outside of Texas, was hospitalized outside of Texas, or recovered from his alleged injuries outside of Texas. *Id.* at ¶¶ 1–169.

And Plaintiff certainly had the opportunity to allege those facts if they were true. When AbbVie filed a motion to dismiss the original complaint, it argued that Texas law applied. In response, Plaintiff filed the First Amended Complaint, which expressly pleads the application of Illinois law. *Id*. at ¶ 14. He did not (and cannot), however, plead non-Texas prescription, review of information, injection, hospitalization, or recovery because those events occurred in Texas.

Therefore, because the "place of injury" is Texas, there is a "***strong presumption***" that Texas substantive law governs this case.

2. *The relevant contacts and principles confirm the strong presumption that Texas law governs.*

Next, the Court must analyze the presumption of Texas law "against the principles of § 6 in light of relevant contacts identified by general provisions like § 145 (torts)." *Paulsen*, 2018 WL 1508532, at *12 (quoting *Townsend v. Sears Roebuck & Co.*, 879 N.E.2d 893, 903 (Ill. 2007)). Under **§ 145**, this Court "should consider, in addition to the place where the injury occurred": (i) the place where the conduct causing the injury occurred; (ii) the domiciles of the parties; and (iii) the place where the relationship, if any, between the parties is centered. *Id*. Moreover, in a personal injury action, the following policy principles in **§ 6** should be considered: (i) the relevant policies of the forum; (ii) the relevant policies of other interested

states and the relative interests of those states in the determination of the particular issue; and (iii) the basic policies underlying the particular field of law. *Id*. Considering these factors and principles as they relate to this matter confirms that Texas has the "most significant relationship" to this case.

First, the conduct causing the alleged injury occurred in Texas, not Illinois. Plaintiff attributes his alleged injury to a series of injections that he was "prescribed and received between March 8, 2018 and April 27, 2018." Am. Compl. at ¶¶ 70-71. As a Texas resident, that prescription and corresponding injections—the cause of his alleged injury—occurred in Texas. *Id*. ¶¶ 70-71.

Plaintiff apparently believes that because "Defendant developed, tested and marketed the subject product in Illinois," that the conduct causing his alleged injury occurred in Illinois. *Id*. at ¶ 14. Courts have rejected this position. In *Paulsen* (a products liability case against an Illinois drug manufacturer), the Georgia plaintiff argued that Illinois was the state where the conduct that caused the injury occurred because the defendant "developed, tested, and marketed" the drug there. *Paulsen*, 2018 WL 1508532, at *12. The court disagreed and stated that it was "unclear" in which state the conduct causing the injury occurred because—despite some relevant conduct taking place in Illinois—the plaintiff took the drug in Georgia, and the drug was manufactured in a foreign country. *Id*. The exact same circumstances are true here—while AbbVie developed, tested, and marketed HUMIRA in Illinois, Plaintiff was prescribed and took it in Texas. Am. Compl. at ¶¶ 7, 70. Moreover, any comparative negligence or other conduct on the part of Plaintiff would have likely occurred in Texas. *See Townsend*, 879 N.E.2d at 906 ("A court's consideration of injury-causing conduct in a section 145 analysis includes all conduct from any

source contributing to the injury.") Thus, at most, the first § 145 factor does not favor either state.

Second, "the domiciles of the parties" factor does not favor either state—AbbVie is domiciled in Illinois, and Plaintiff is domiciled in Texas. *See* Am. Compl. at ¶¶ 7-8; *see also Paulsen*, 2018 WL 1508532, at *12 ("The domicile factor also does not point strongly to any one state, as Plaintiff is a Georgia resident, and Abbott is an Illinois resident.")

Third, "the place where the relationship, if any, between the parties is centered" is in Texas because that is where Plaintiff took HUMIRA. *See Paulsen*, 2018 WL 1508532, at *12 ("The parties' relationship is centered in Georgia, as this is where Plaintiff was injected with Lupron."); *see also Nichols v. G.D. Searle and Co.*, 668 N.E.2d 1101, 1103 (Ill. App. Ct.1996) (holding that the relationship between parties was centered in the state where the device "was prescribed and used").

Finally, the policy principles listed in § 6 do not overcome the presumption of Texas law and the application of Section 82.007. Indeed, the application of Section 82.007 to the facts of this case furthers the very policy interests underlying the Texas statute: to discourage lawsuits against drug manufacturers whose drugs are accompanied by an FDA-approved label. *See* J. Hardin & K. Mackillop, *Despite Levine, Section 82.007 - and Its Limitations on Pharmaceutical Warnings Claims - Remains Alive and Well in Texas*, 72 Tex. B.J. 356, 357 (2009) (quoting Debate on H.B. 4, 78th Leg., R.S. 74-75 (March 27, 2003)). Texas, therefore, has a strong policy interest in having its law applied in a case brought by one of its citizens against an FDA-approved drug.

Conversely, in cases like this involving a non-resident plaintiff who was injured in a state other than Illinois, allegedly by a product that was sold and used outside of the state, Illinois's

policy interest in having its products liability laws applied is slight, if any at all. *See* *Fisher v. Brilliant World Int'l*, No. CIV.A. 10 C 2381, 2011 WL 3471222, at *4 (N.D. Ill. Aug. 4, 2011) ("Illinois's interest in the case consists mainly of protecting and compensating an injured ***resident***. Illinois also has an interest in ensuring safe ***products are sold within the state***. However, this interest is slight because the tube at issue was not intended to be used in Illinois.") (emphasis added). As stated above, Plaintiff is a resident of Texas, and the HUMIRA at issue was sold in Texas. Therefore, § 6's policy principles do not tip the scales in support of applying Illinois law.

After analyzing the § 145 contacts and § 6 policy principles, the "strong presumption" that Texas law applies herein is not overcome in favor of Illinois law. On the contrary, the presumption is conclusively borne out. Texas substantive law is the proper choice in this case.[5]

B. All of Plaintiff's Claims are Warnings-Based Product Liability Claims Under Texas Law.

Plaintiff's entire case is based on a failure to warn theory. This is important because, as seen below (*infra* pt. IV.C), any "warnings or information" based claims against an FDA-approved drug like HUMIRA are subject to a statutory presumption of non-liability.

Texas law delineates three types of product liability defects: (1) marketing defect, (2) design defect, and (3) manufacturing defect. *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 382 (Tex. 1995). Relevant to the allegations here is a "marketing defect," which is premised on a defendant's failure to warn. *Romo v. Ford Motor Co.*, 798 F.Supp.2d 798, 807 (S.D. Tex. 2011)

[5] *See also Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 865–66 (7th Cir. 2010) (applying Illinois choice-of-law principles and holding that Virginia law governed in a case where plaintiff ingested the drug in Virginia and was administered initial medical treatment in Virginia); *Gray v. Abbott Laboratories, Inc.*, 2011 WL 3022274, at *3 (N.D. Ill. July 22, 2011) (applying Georgia substantive law because the product was purchased and the injury occurred in Georgia).

("A 'marketing defect' occurs when a defendant knows or should have known of a potential risk of harm presented by the product but markets it without adequately warning of the danger or providing instructions for safe use.").

Despite labeling some of his causes of action otherwise, Plaintiff's entire theory of the case is based on a marketing defect (*i.e.*, the failure to warn of kidney failure and/or ILD). For purposes of this Motion, Plaintiff's Amended Complaint is broken down into two parts: Factual Allegations (¶¶ 15-77) and Causes of Action (¶¶ 78-163). While the Factual Allegations are completely unfounded, they nevertheless advance only ***one*** factual theory of liability—that AbbVie knew HUMIRA could cause kidney failure and/or ILD and never warned of those complications. Am. Compl. at ¶¶ 19-69.

This is Plaintiff's theory of the case. And while he rattles off a few legal terms of art in his Negligence claim such as "design, unreasonably dangerous, and manufacture," Plaintiff never alleges a single fact to support those buzzwords. *See infra* pt. IV.D.1; *see also Phares v. Actavis-Elizabeth LLC*, 892 F.Supp.2d 835, 839 (S.D. Tex. Aug. 30, 2012) ("Texas law considers most of the foregoing claims [including negligence, strict liability, and fraud] as failure to warn [products liability] claims.") (also citing to Tex. Civ. Prac. & Rem. Code § 82.001(2)); *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 168-69 (Tex. 2012) (dismissing strict products liability, negligence, breach of implied warranty of merchantability, misrepresentation, and consumer fraud claims on the grounds that they were actually based on the manufacturer's failure to warn); *Romero v. Wyeth Pharmaceuticals, Inc.*, Civ. Action No. 1:03-CV-1367, 2012 WL 12547449, *2-3 (E.D. Tex. Aug. 31, 2012) ("In short, '[i]f [a] claim is based upon [a product's] labeling, its omissions, or inaccuracies, it falls under this purview of the … Texas Civil Practices and Remedies Code provision[].'").

Further, despite inadequate factual averments to support it, the Amended Complaint includes a claim which is titled "Negligent Failure to Test." Am. Comp. at ¶¶ 134-141. However, given the applicable Texas statute in this case, a negligence claim based on a failure to test can only be viable if Plaintiff Bowles's underlying factual allegations stand separate and apart from his warnings-based claims. *See Romero*, 2012 WL 12547449, at *4 (distinguishing a "negligence cause of action based upon Wyeth's failure to test, ***a claim that does not pertain to any purportedly inadequate warnings*** issued by Wyeth.") (emphasis added). In the instant matter, Plaintiff's Negligent Failure to Test claim ***does pertain*** to what allegedly should have been included in HUMIRA's warnings. Am. Compl. ¶¶ 140-141 (in alleging causation for his Negligent Failure to Test claim, Plaintiff alleges that AbbVie's failure to test "caused [him] to ***unknowingly*** take a product that was not . . . safe" and that the failure to test resulted in "negligent ***misrepresentations*** . . . .") (emphasis added).

Therefore, under Plaintiff's Negligent Failure to Test theory, he will have to prove, among other facts or elements, that: (1) had AbbVie "adequately" tested HUMIRA then it would have discovered a link to kidney failure and/or ILD, and (2) the failure to test caused Plaintiff's injuries because he took HUMIRA without knowing of inadequately-tested risks (i.e., AbbVie failed to warn him). Plaintiff's Negligent Failure to Test claim, therefore, is "inextricably intertwined" with HUMIRA's warnings and is thus a warnings-based claim. *American Tobacco Co., Inc. v. Grinnel*, 951 S.W. 2d 420, 437 (Tex. 1997) ("The Grinnells' negligent testing claim is predicated on American's duty to test and ascertain the dangers inherent in its products about which it must warn consumers. Because the negligent testing claim is inextricably intertwined with the Grinnells' negligent failure to warn claim, we hold that summary judgment was also proper on this claim . . . ."); *see also Romero*, 2012 WL 12547449, at *4 ("Romero's negligent

failure to test claim survives Wyeth's motion [for summary judgment]. Romero is cautioned, however, that she must confine her evidence at trial to the issue of inadequate testing. Evidence pertaining to warnings or lack of warnings issued by Wyeth will not be permitted.") (emphasis added); *Parchim v. Biogen Inc.*, 6:19-CV-00524, 2019 U.S. Dist. LEXIS 232810 (W.D. Tex. Dec. 5, 2019) (dismissing failure to test claim where "the Court agree[d] with Biogen that 'Plaintiff's supposed failure-to-test claim is just a failure to warn claim dressed up in sheep's clothing.'"). Simply put, this is a warnings case in its entirety.

C. All of Plaintiff's Claims Fail Under Section 82.007.

Texas law creates a rebuttable presumption that a manufacturer of an FDA-approved drug, like HUMIRA, is not liable for "warnings or information":

> (a) In a ***products liability action alleging that an injury was caused by a failure to provide adequate warnings or information*** with regard to a pharmaceutical product, there is a ***rebuttable presumption that the defendant . . . [is] not liable*** with respect to the allegations involving failure to provide adequate warnings or information if:
>
> (1) the warnings or information that accompanied the product in its distribution were those ***approved by the United States Food and Drug Administration*** . . . .

Tex. Civ. Prac. & Rem. Code Ann. § 82.007 (a)(1) (emphasis added). Plaintiff may only rebut this presumption with sufficient proof of one of these five scenarios: (1) AbbVie committed fraud on the FDA; (2) AbbVie sold HUMIRA after the FDA ordered it removed from the market; (3) AbbVie promoted HUMIRA for an unapproved use and that use caused the injury; (4) AbbVie prescribed HUMIRA for an unapproved use and that use caused the injury; or (5) AbbVie bribed an FDA official, causing the FDA-approved warnings to be inadequate. *Id*. at § 82.007 (b)(1 – 5); *Gonzalez v. Bayer Healthcare Pharms.,*930 F.Supp.2d 808, 820 (S.D. Tex.

2013). Even assuming every allegation in Plaintiff's Amended Complaint is true, Section 82.007 bars all of Plaintiff's claims as a matter of law.

1. *HUMIRA's Warnings Were Approved by the FDA, so AbbVie is Entitled to the Rebuttable Presumption in Section 82.007 (a)(1).*

AbbVie is entitled to the rebuttable presumption laid out in subsection (a)(1) because the FDA approved HUMIRA's warnings that are at issue in this case. Indeed, Plaintiff admits in his Amended Complaint that the FDA approved HUMIRA on December 31, 2002 (Am. Compl. at ¶ 20), that HUMIRA was subject to continuing post-approval FDA oversight and regulations (*id*. at ¶¶ 45-53) and that Plaintiff used HUMIRA treat psoriatic arthritis (an FDA-approved indication). *Id*. at ¶ 71. More importantly, as part of the approval and post-approval process, the FDA not only approved HUMIRA's original label in December 2002 but also approved over fifty supplements to the HUMIRA label (the last being on 2/24/2021).[6]

Here, Plaintiff allegedly took HUMIRA between March – April 2018. Am. Compl. at ¶ 70. The HUMIRA label in effect at that time was approved by the FDA on December 14, 2017.[7] AbbVie is entitled to the presumption that it is not liable for "failure to provide adequate warnings or information . . . ." § 82.007 (a).

[6] U.S. Food and Drug Administration Website, Approval Date(s) and History, Letters, Labels, Reviews for BLA 125057, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125057 (last visited Mar. 16, 2021).

[7] U.S. Food and Drug Administration, Supp. Approval Letter for HUMIRA (Dec. 14, 2017) *available at* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/125057Orig1s403ltr.pdf, attached as **Exhibit B**. Moreover, a copy of the December 2017 FDA-Approved HUMIRA label, which is attached as **Exhibit C**, can be accessed here: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125057s403lbl.pdf

2. *Plaintiff Has Not Alleged—And Indeed Cannot—Any Legally Valid Exception to AbbVie's Presumption of Non-Liability.*

Plaintiff cannot rebut AbbVie's presumption of non-liability because the only possible statutory exception[8] Plaintiff could attempt to cling to—that AbbVie withheld or misrepresented information to the FDA regarding HUMIRA (*i.e.*, that AbbVie committed "fraud on the FDA") under § 82.007(b)(1)—is unavailable unless there has been an actual FDA finding of fraud. *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 380 (5th Cir. 2012). There has been no such finding of fraud, so the only possible rebuttal to AbbVie's presumption of non-liability is inapplicable.

In *Lofton*, the Fifth Circuit affirmed the dismissal of a failure-to-warn claim despite the plaintiff's invocation of subsection (b)(1), finding that this statutory exception is the type of fraud-on-the-FDA provision preempted by the FDCA. *See id.* The crux of subsection (b)(1) lies in the FDCA disclosure mandates, which requires evidence that the manufacturer withheld from the FDA "required information that was material and relevant." *Id*. at 379. The Fifth Circuit reasoned that "[t]he term 'required information' refers to federal requirements under the FDCA; what is 'material' and 'relevant' must be determined by FDA itself, not by state court juries." *Id.* Therefore, subsection (b)(1) exists "solely by virtue of the FDCA disclosure requirements[,]"

[8] The other exceptions in Texas Civil Practice and Remedies Code § 82.007(b) (b)(2 – 5) are inapplicable because Plaintiff has not plead any facts to support them:

§ 82.007(b)(2):	There is no allegation that AbbVie sold HUMIRA after the FDA ordered HUMIRA off the market (HUMIRA is still on the market).
§ 82.007(b)(3):	Plaintiff admits that he took HUMIRA for an approved indication (psoriatic arthritis).
§ 82.007(b)(4):	There is no allegation that AbbVie prescribed HUMIRA (because a drug like HUMIRA may only be prescribed by a licensed physician), and Plaintiff admits that he took HUMIRA for an approved indication (psoriatic arthritis).
§ 82.007(b)(5)	There is no allegation that AbbVie bribed a public official under 18 U.S.C. § 201 to keep references to kidney failure and/or ILD out of HUMIRA's labels.

which, according to the Supreme Court, warrants preemption. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001).

In concluding its analysis, the Fifth Circuit considered the policy concerns underlying the Supreme Court's *Buckman* decision and determined that those policies would be furthered by preempting subsection (b)(1). *Lofton*, 672 F.3d at 380. Specifically, the concern is that if state-law claims proceed despite contrary law or regulation then (1) manufacturers would flood the FDA with information to ensure they retain the state-law presumption of non-liability, which takes away the FDA's control to "intelligently limit" disclosures and (2) the FDA's processes would be invaded when close questions of "withholding" information or "misrepresentations" arose. *Id.* Therefore, the Fifth Circuit held that Section 82.007(b)(1) "is preempted unless the FDA itself has found fraud." *Id.*

AbbVie anticipates that Plaintiff will attempt to side-step the preemption of (b)(1) by asking the Court to apply an irrelevant Second Circuit Court of Appeals decision from 2006 to the Texas statute at issue in this case. To the extent Plaintiff makes these arguments they should be rejected—which is what the other Federal Circuit Court of Appeals have done that have considered the issue.

Specifically, Michigan law provides an absolute defense to ***all*** product liability claims (as opposed to just warnings, like in Texas) for manufacturers of FDA-approved drugs. *See* Mich. Comp. Laws. § 600.2946 (5). In 2006, the Second Circuit in *Desiano* was tasked with deciding whether subsection (a) of Michigan's statute was preempted under *Buckman*. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d. Cir. 2006). The Second Circuit determined that it was not—holding that the plaintiff was permitted to bring products liability claims against the defendant because (1) there is a federal presumption against preemption, (2) the plaintiff's claims

were traditional products liability claims, which do not require evidence of "fraud on the FDA," and (3) the Michigan statute creates an affirmative defense, which means "fraud on the FDA" is not a required element of Plaintiff's claims. *Id*. at 93-96.

The Second Circuit's *Desiano* decision has been rejected by two federal circuits since it was decided. First, the Sixth Circuit held that subsection (a) of the Michigan statute was preempted under *Buckman* and thus affirmed the dismissal of the plaintiff's claims. *Marsh v. Genentech, Inc.*, 693 F.3d 546, 551-54 (6th Cir. 2012)[9]. Second, and as discussed above, the Fifth Circuit in *Lofton*—which is the ***only*** federal circuit court to address the Texas statute—held that § 82.007(b)(1) was preempted under *Buckman*. 672 F.3d at 380. In reaching this decision, the Fifth Circuit closely scrutinized and rejected *Desiano's* analysis—stating that "[i]n cases like this, where the FDA has not found fraud, the threat of imposing state liability on a drug manufacturer for defrauding the FDA intrudes on the competency of the FDA and its relationship with regulated entities." *Id*. This Court should follow the only federal circuit court to address the issue and find that subsection (b)(1) is preempted. *See also Atkinson v. Luitpold, Pharms., Inc.*, 448 F.Supp.3d 441 ("Although this Court is not bound by the Fifth Circuit's rulings, it bears consideration that the Fifth Circuit, which is conversant with Texas law, found that the presumption against preemption did not apply in a Section 82.007(b)(1) case."). Accordingly, because Plaintiff does not allege that the FDA has made a finding of fraud against AbbVie regarding HUMIRA,[10] subsection (b)(1) is inapplicable here.

[9] The Sixth Circuit in *Marsh* refused to consider the Second Circuit's analysis from *Desiano*—stating in a footnote that it would follow the Sixth Circuit's prior decisions on the issue. *Id*. at n. 6.

[10] As discussed above, Plaintiff can only state a claim by alleging that there was an agency finding by the FDA that AbbVie had defrauded it regarding HUMIRA. AbbVie raised this very issue in its original motion to dismiss, yet Plaintiff did not add an FDA-finding-of-fraud allegation to the First Amended Complaint. Plaintiff did, however, include the following allegation on the first page of his Amended Complaint: "In 2017, the FDA issued a Form 483 Inspection Citation to Defendant for underreporting

Plaintiff has now twice attempted to plead around Section 82.007, and he simply cannot do it. Dismissal ***with prejudice*** is appropriate. *See Atkinson*, 448 F. Supp.3d at 452 (granting the defendant's Rule 12(b)(6) motion and holding that because the "rebuttable presumption in Section 82.007(a)(1) applies here, and because Plaintiff's only argument to rebut the presumption is preempted, [the plaintiff's five claims based on failure to warn] shall be dismissed with prejudice."); *Parchim v. Biogen Inc.*, No. 619CV00524ADAJCM, 2019 WL 9654875, at *2 (W.D. Tex. Dec. 5, 2019) ("Under Texas law, if the claim is based on the product's labeling, its omissions, or inaccuracies, it falls under the purview of Section 82.007 regardless of how it is pleaded.").

D. To the Extent Any of Plaintiff's Claims Are Not Premised on Failure-To-Warn, Dismissal is Still Required.

While AbbVie maintains that *all* Plaintiff's claims are premised on assertions regarding HUMIRA's labeling, its omissions, or inaccuracies, Plaintiff's severely truncated legal descriptions allege various conduct by AbbVie in passing. Out of an abundance of caution, AbbVie addresses those allegations below.[11]

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death complaints regarding HUMIRA." Am. Compl. at ¶ 2. To the extent Plaintiff is attempting to parlay this one-off Form 483 allegation into some sort of implication that the FDA has made a finding of fraud against AbbVie, he misses the mark. A Form 483 citation is not an agency determination. *In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31, 35 (1st Cir. 2014) ("A Form 483 contains advisory language that make[s] clear it lists only 'inspectional observations and do[es] not represent a final agency determination regarding your compliance.'"); *see also* U.S. Food and Drug Administration Website, FDA Form 483 Frequently Asked Questions,https://www.fda.gov/inspections-compliance-enforcement-and-criminal investigations/inspection-references/fda-form-483-frequently-asked-questions (last visited Mar. 17, 2021) ("The FDA Form 483 does not constitute a final Agency determination of whether any condition is in violation of the FD&C Act or any of its relevant regulations.").

[11] AbbVie submits that Plaintiff's claims for Strict Liability—Failure to Warn; Breach of Implied Warranty; Breach of Express Warranty; Fraud; and Negligent Misrepresentation are based solely on HUMIRA's "warnings and information." § 82.007(a). To the extent those claims are based on some other theory of liability, AbbVie lacks "fair notice" of those theories because they are not discernable from the face of the Complaint. *Fields*, 2020 WL 5296926, at *3 (quoting *Twombly*, 550 U.S. at 555).

1. *Negligence/Gross Negligence.*

Plaintiff's cause of action titled "Negligence" (Am. Compl. at ¶¶ 81-119) is nearly incomprehensible. In part, it reads as follows:

> At all times herein, Defendant negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, distributed marketed, labelled, packaged, prepared for use and sold HUMIRA. . . . .
>
> Defendant breached its duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promotion, marketing, advertisement, packaging, sale, testing, quality assurance, quality control, sale, and distribution of HUMIRA in interstate commerce, in that Defendant knew and had reason to know that a consumer's use and injection of HUMIRA created a significant risk of suffering unreasonably dangerous health related side effects, including Petitioner's injuries, and failed to prevent or adequately warn of the severity of these risks and injuries.

Id. at ¶¶ 84; 94. Without copying and pasting every single paragraph, AbbVie submits that Plaintiff's Negligence claim, in its entirety, fails to plausibly allege ***any*** factual content that puts AbbVie on "fair notice" of the basis of this claim (other than failure to warn). *Fields*, 2020 WL 5296926, at *3 (quoting *Twombly*, 550 U.S. at 555). For instance, there are multiple passing references to buzzwords such as "design", "manufacture", and "unreasonably dangerous" (*see* ¶¶ 83, 84, 90, 94, 95, 96, 97, 104), but there are no factual allegations describing how AbbVie was negligent in designing, or manufacturing HUMIRA. Each assertion is simply a one-word allegation in a laundry list of alternative theories that could be recycled into any "dangerous drug" complaint in the country. This lack of factual enhancement renders any such arguable claim nonactionable. *See Murthy v. Abbott Labs.*, 847 F. Supp. 2d 958, 977 (S.D. Tex. 2012) (dismissing negligence claim based on failure to test HUMIRA where plaintiff did "not plead any facts to support [negligence claims]" beyond failure to warn).

Further, because dismissal of the Negligence claim is required, so too must Plaintiff's Gross Negligence claim be dismissed. Am. Compl. at ¶¶ 149-162. Under Texas law, a gross negligence claim cannot stand independently without a negligence claim. *See Schouest v. Medtronic, Inc.*, 92 F. Supp. 3d 606, 613 (S.D. Tex. 2015) ("Because the court has dismissed all negligence claims upon which gross negligence could be predicated, it must also dismiss [plaintiff]'s gross negligence claim."); *Trevino v. Lightning Laydown, Inc.*, 782 S.W.2d 946, 949 (Tex. App. 1990), *writ denied* (May 9, 1990) ("[O]ne's conduct cannot be grossly negligent without being negligent.")

Therefore, to the extent Plaintiff's Negligence and Gross Negligence claims purportedly include any claims other than those premised on failure to warn, such claims require dismissal for failure to satisfy the requisite pleading standard.

2. *Negligent Failure to Test.*

Although AbbVie has demonstrated that Plaintiff's Negligent Failure to Test claim is "inextricably intertwined" with warnings, *see supra* pt. IV.B, which requires dismissal, an additional reason exists for the Court to dismiss the claim. Specifically, Plaintiff does not set forth requisite factual content to support it. Plaintiff, rather, simply recites the elements:

> 135. Defendant ***has a duty to adequately test*** its products to ensure that their drugs are not unreasonably dangerous to its consumers.
>
> 137. ***Defendant had notice of HUMIRA's propensity to cause kidney injury and interstitial lung disease*** through Adverse Event reports, case studies, and other reporting and/or research.
>
> 138. Defendant ***failed to perform reasonable testing*** of HUMIRA's link to kidney injury and interstitial lung disease, all the while continuing to place HUMIRA in the stream of commerce.

> 139. The ***failure to [perform reasonable testing]*** deprived consumers, including Petitioner, of a reasonably safe product.
>
> 140. Defendant's willful blindness ***caused Petitioner to unknowingly take a product*** that was not reasonably and adequately tested for known risks . . . .

Am. Compl. at ¶¶ 135-140. These allegations, without facts alleging "how" AbbVie was negligent and "how" AbbVie's negligent conduct proximately caused Plaintiff's injuries, are not sufficient to state a claim for relief. *Grzanecki v. Smith & Nephew, Inc.*, No. 18-CV-00204, 2019 WL 2297452, at *2-3 (N.D. Ill. May 30, 2019).

3. *Breach of Express Warranty.*

Plaintiff's express warranty claim does not identify any specific affirmation of fact or promise that AbbVie breached—other than a conclusory allegation that AbbVie warranted "that HUMIRA is safe, effective, fit and proper for its intended use." Am. Compl. at ¶ 126. Under Texas express warranty law, Plaintiff is required to prove "that [AbbVie] made a ***specific*** promise or affirmed a ***specific*** fact." *City of Port Arthur v. Daimler Buses N. Carolina, Inc.*, No. 1:15-CV-00186-MAC, 2018 WL 3596863, at *3 (E.D. Tex. July 12, 2018) (emphasis in original). Plaintiff's Complaint does not set forth any alleged facts regarding the specifics of the contents of AbbVie's alleged warranty, nor is it clear whether the alleged warranties were made to Plaintiff himself or his prescribing physician. *See Gonzalez v. Bayer Healthcare Pharm., Inc.*, 930 F. Supp. 2d 808, 818 (S.D. Tex. 2013) ("Plaintiff's breach of warranty claims are also subject to the learned intermediary doctrine claims. She fails to state a plausible claim because she does not allege what warranties were made to her prescribing physician nor state how they were breached, leaving only 'an unadorned, the defendant-unlawfully-harmed-me accusation.'"); *Steen v. Medtronic, Inc.*, No. 310-CV-936-L, 2010 WL 2573455, at *3 (N.D. Tex. June 25, 2010) (dismissing complaint where plaintiff did not "allege any facts showing when and how he

received notice of such warranties" or "fact showing the pacemaker did not comport with such warranties").

Moreover, AbbVie never made any promises to physicians or patients—expressly or impliedly—about any specific outcomes, such as guaranteed benefits or a lack of side effects. To the contrary, the labeling, which was and remains FDA-approved, warned of the risks and benefits associated with HUMIRA so that the prescribing physician could make the decision about whether the medication was appropriate for a particular patient.

V. CONCLUSION

All eight of Plaintiff's claims, despite how Plaintiff has chosen to title them, are effectively one theory—failure to warn. As such, each claim fails as a matter of law either entirely under the presumption of Section 82.007, or individually as stand-alone claims. Accordingly, AbbVie respectfully requests that the Court dismiss Plaintiff's Amended Complaint in its entirety with prejudice because any possible amendment, like the present effort, would be futile under Texas law. *Vargas-Harrison v. Racine Unified Sch. Dist.*, 272 F.3d 964, 974 (7th Cir. 2001) ("[W]e nevertheless must affirm the dismissal because an examination of the proposed amended complaint . . . make[s] clear that the amendment would have been futile.")

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 18, 2021, the foregoing document was filed using the Court's CM/ECF system, which will send notification of this filing to all attorneys of record who have registered for CM/ECF updates.

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